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INTERNATIONAL SEARCHING AUTHORITY

To:

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)Date of mailing
(day/month/year) see form PCT/ISA/21C (second sheet)Applicant's or agent's file reference
see form PCT/ISA/220FOR FURTHER ACTION
See paragraph 2 belowInternational application No.
PCT/US2006/019959International filing date (day/month/year)
23.05.2006Priority date (day/month/year)
23.05.2005International Patent Classification (IPC) or both national classification and IPC
INV. A61B10/00
ADD. A61B17/32 A61B17/34Applicant
SENORX, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Date of completion of
this opinionsee form
PCT/ISA/210

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/US2006/019959

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material:

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material:

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing:

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3,4,11-16,22-26,31-36,39-42
	No: Claims	1,2,5-10,17-21,27-30,37,38
Inventive step (IS)	Yes: Claims	
	No: Claims	3,4,11-16,22-26,31-36,39-42
Industrial applicability (IA)	Yes: Claims	1-42
	No: Claims	

2. Citations and explanations**see separate sheet**

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Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1 Reference is made to the following documents:

- D1: US-B1-6 258 111 (ROSS ROD ET AL) 10 July 2001 (2001-07-10)
- D2: US 2004/167428 A1 (QUICK RICHARD L ET AL) 26 August 2004 (2004-08-26)
- D3: US 2003/229293 A1 (HIBNER JOHN A ET AL) 11 December 2003 (2003-12-11)
- D4: US-A-5 106 364 (HAYAFUJI ET AL) 21 April 1992 (1992-04-21)

2 Novelty

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document D1 discloses (the references in parentheses applying to this document):

A tissue-cutting member (490) for separating a tissue specimen from a target within a patient's body (col. 3, l. 49-58) comprising:

- a. a distal tubular portion (490) having a distal tip (494) with an outer tissue-cutting edge, an inner tissue-receiving aperture and a longitudinal axis (cf. fig. 28);
- b. a longitudinally oriented opening (492) in the distal tubular portion that has an open distal end which opens to the inner tissue receiving aperture and a closed proximal end (cf. fig. 28); and
- c. at least a second opening (492) in a wall of the distal tubular portion circumferentially spaced from the longitudinally oriented opening about the longitudinal axis (cf. fig. 28).

2.2 Dependent claims

Dependent claims 2, 5-10, 17-21, 27-30, 37 and 38 do not contain any features

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which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, see document D1 and the corresponding passages cited in the search report.

3 Inventive Step

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 3, 4, 11-16, 22-26, 31-36 and 39-42 does not involve an inventive step in the sense of Article 33(3) PCT (see documents D2, D3, and D4 and the corresponding passages cited in the search report).

- 3.1 In particular, the additional features of claims 3 and 31 concerning the circular shape and location of the closed proximal end of the longitudinally oriented opening is merely one of several straightforward possibilities from which the skilled person would select (e.g. D2), in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem of facilitating flaring of the distal section of the cutting member.
- 3.2 The additional features of claims 4, 11, 15, 16 and 23 concerning the shapes of the second and fourth openings are merely straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem of providing stress relief and facilitating radial expansion or contraction of the cutting member.
- 3.3 The additional features of claims 12-14, 22 and 24-26 and concerning the locations of the longitudinally oriented, second, third, fourth and fifth openings are merely straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem of maintaining an efficient vacuum application within the biopsy device.
- 3.4 The additional features of claims 32-34 and 39-42 concerning the bevelled front face of the distal tip of the cutting member are described in document D2 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal design option to include these features in the tissue cutting

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instrument described in document D1 in order to solve the problem of providing a cutting member with improved cutting ability.

- 3.5 The additional features of claims 35 and 36 concerning the material of the cutting member are described in document D2 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal design option to include these features in the tissue cutting instrument described in document D1 in order to solve the problem of providing a cutting member with improved strength.

4 Further remarks

- 4.1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.
- 4.2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).